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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,053	07/24/2003	Claus Yding Andersen	6203.214-US	1429
Reza Green 7590 Novo Nordisk Pharmaceuticals, Inc. 100 College Road West Princeton, NJ 08540			EXAMINER SAUCIER, SANDRA E	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 03/11/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/626,053

**Applicant(s)**

ANDERSEN ET AL.

**Examiner**

Sandra Saucier

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 44-59 is/are pending in the application.  
4a) Of the above claim(s) 51-55, 57 and 58 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 44-50, 56 and 59 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 24 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Applicant has canceled all examined claims and has presented all new claims. Claims 44-59 are pending. Claims 44-50, 56, 59 to the extent that they read on the elected species are under examination.

***Election/Restriction***

Applicants elected species of FF-MAS for examination 7/10/06.  
Applicants elected Group II, directed to the use of growth factor in a process of in vitro fertilization on 1/22/08.

***Claim Rejections – 35 USC § 112***

**INDEFINITE**

Claims 44-50, 56, 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Please do not use abbreviations in the claims at least without prior definition in the claims.

Claim 44 uses “MAS” which is not defined.

Claim 47 uses abbreviations “FSH” and “EGF” which are without definition.

Claim 47 uses parenthetical enclosures. It cannot be determined if these are meant to further limit or to expand the preceding phrases.

Claims 44-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Example 2 is directed to the implantation of human zygotes cultured in FSH and EGF medium. It is assumed that the claimed method is related to this example. However, after *in vivo* maturation of the oocytes due to injections of FSH, hCG, the oocytes were recovered. It is assumed that the oocytes directly recovered from the female are not in MII. Thus, the culturing of oocytes in the example is not a culturing of MII oocytes as required by the claim language. The recovered oocytes are cultured EGF and FSH for 24 hours during which time they progress to MII. After 24 hours, the medium containing the EGF and FSH is removed and the oocytes are placed in a medium which does not contain these supplements and cultured further for 48 more hours at the end of this time, zygotes are formed. It appears that a sometime during the first 24 hour culture with EGF and FSH, sperm is added, although there is no disclosure as to when this step is performed. It is doubtful that the sperm are added at the beginning of the culture step. In any case, this does not appear to be the method now claimed where the oocytes are said to be MII oocytes and the FSH and EGF are said to be present with MII oocytes and sperm until zygotes are formed. Clarification of the example and correlation with the claimed method are requested. Until this is done, a written description rejection of the claimed method is made.

***Claim Rejections – 35 USC § 102***

Claims 44–47, 50, 56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Park *et al.* [U].

The claims are directed to a method for *in vitro* fertilization comprising: culturing cumulus enclosed oocytes in metaphase II with spermatozoa in a culture medium which contains an additive which is a growth factor, thereby forming zygotes.

Park *et al.* disclose an *in vitro* method of culturing and maturing oocytes in a culture medium which contains EGF and sperm and allowing the zygotes to develop, page 476, Experiment 1.

Claims 44–50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Illera *et al.* [V].

Illera *et al.* demonstrate maturation and culturing of oocytes in a medium which contains EGF, FSH and sperm and allowing zygotes to develop.

***Claim Rejections – 35 USC § 103***

Claims 44–47, 50, 56, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ben-Yosef *et al.* [W].

The claims have been discussed above.

Ben-Yosef *et al.* disclose a method of *in vitro* fertilization comprising induction of ovulation (maturation) *in vivo* by injection of the intact animal with PMSG and hCG, harvesting the oocytes, incubating the oocytes with EGF, transferring the oocytes to a sperm suspension for fertilization (Materials and methods, page 136).

The reference lacks the continuous exposure of the oocytes to EGF during fertilization and zygote development.

In the absence of evidence of criticality, one of ordinary skill in the art may mature the oocyte in a medium containing a compound which assists maturation before transferring into a medium which does not contain such a compound for fertilization and zygote development.

Concentrations of compounds are *prima facie* obvious in the absence of criticality, See MPEP 2144.05II.

Claims 44–50, 56, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Illera *et al.* [V].

The claims have been discussed above.

Although Illera *et al.* matures the oocytes *in vitro* instead of *in vivo*, the oocytes will enter MII prior to fertilization. Thus, under this interpretation, all of the limitations of the claimed method are present in the method of the reference. One of skill in the art may mature the oocytes *in vitro* or *in vivo* to cause them to enter MII prior to fertilization in the absence of evidence to the contrary. Variation in the concentration of compounds is *prima facie* obvious, see MPEP 2144.05 I. and II. Also, in the absence of evidence of variation in mammals with regard to the response to growth factors and hormones, use of the same hormone/growth factors with mouse, bovine, porcine or human oocyte maturation and fertilization protocol would be obvious.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see

<http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/

Primary Examiner, Art Unit 1651